



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,295	05/17/2005	Aleksander Resman	RG/G-33025A/Lek	9703
83721	7590	05/21/2010	EXAMINER	
Lek (Slovenia) - LUEDEKA, NEELY & GRAHAM, P.C. P.O. BOX 1871 Knoxville, TN 37901			ARNOLD, ERNST V	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			05/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/521,295	Applicant(s) RESMAN ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 May 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 13 May 2010. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☒ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1-5,7-9,12-18 and 20.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/Ernst V Arnold/
 Primary Examiner, Art Unit 1616

Continuation of 3. NOTE: Independent claim 1 now recites a humidity limitation and a particle size limitation that were not previously presented. Also the particle size is now limited to about 30 microns which changes the scope of the claim. Independent claim 20 now recites 'at least 10% of a second film forming agent' which was not previously presented. These limitations require further search and consideration before a patentability determination can be made. Claim 20 recites "at least 10% of a second film-forming agent". There is no support in the specification as filed for "at least 10% of a second film-forming agent" and therefore this represents a new concept and is new matter. Original claim 15 recites: "the coating contains at least about 10% of a polymer having viscosity of up to about 15 mPas." ; but does not provide support for the instant recitation.

Continuation of 11. does NOT place the application in condition for allowance because: While Applicant's amendments would overcome the 112 first paragraph new matter over the particle size and scope of enablement as well as the 112 second paragraph, however the other 112 first paragraph new matter rejection is maintained. With respect to the capsule, there is not *ipsis verbis* support for a capsule. A capsule carries with it a certain meaning in the pharmaceutical art. Applicant discloses in [0017] that is difficult to encapsulate the micronized form. This could mean that the micronized particles are coated with some film forming polymer to encapsulate them. In fact, in claim 20, a film coating is applied over the tablet core which is a form of encapsulation. In other words, the process of encapsulation does not necessarily mean the resulting product is a capsule per se. A capsule in the pharmaceutical arts is an enclosing structure that encloses a dose of medicine such as a hard or soft gelatin capsule. Nowhere in the specification as filed are such 'capsules' disclosed and thus this represents a new concept and is new matter. With respect to the 103 rejection, Applicant has amended the claims with new limitation that require further search and consideration as, for example, the primary reference of Broad does not expressly teach drying to a final humidity of about 2.5%.

Respectfully, the claims will not be entered because they are not in condition for allowance for at least the reasons provided above.